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Croatia

Agricultural Biotechnology Annual

General Report

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Report Highlights:

Croatia is a net food importer and the government policy is geared towards raising agricultural productivity and, to a lesser extent, control imports. Although Croatia has adopted the European Union's (EU) biotech legislation, Croatia remains part of a group of EU member states that maintain more stringent national biotech policies than the EU norm. Croatia believes its competitive advantage in agricultural products will be realized via quality not quantity and equates this with organic production. Additionally, Croatian politicians and the general public remain misinformed about biotech products and view them as dangerous and unnatural.

Section I. Executive Summary:

Croatia is a net food importer. The primary goal of agricultural policy is to increase productivity, and to a lesser extent, control imports.

Although Croatia has adopted the EU's biotech legislation, Croatia remains part of a group of EU member states that maintain more stringent national biotech policies than the EU norm. Croatia believes its competitive advantage in agricultural products will be realized via quality not quantity and equates this with organic production. Additionally, Croatian politicians and the general public remain misinformed about biotech products and view them as dangerous and unnatural. In 2004 and 2005, the government randomly tested foods and seeds. Several products had to be withdrawn from the market due to a lack of proper biotech labeling. Croatia now regularly tests products for biotech events at the border and in the market. The testing is performed in accordance with Croatia's annual inspection plans for Sanitary Inspection, which is determined based on available fiscal resources

Several pieces of legislation regulate the importation and cultivation of biotech crops and foods. The laws regulating biotechnology include the Law on Genetically Modified Organisms (GMOs), the Law on the Application of EU Regulation 1829/2003 on GMO Food and Feed and Regulation 1830/2003 on Traceability and Labeling of Food and Feed Derived from GMOs that Amends EU Directive 2001/18/EC, the Law on the Application of EU Regulation 1946/2003 on Trans-boundary Movement of GMOs and the Food Act.

Croatia's law on GMOs bans the release of genetically engineered (GE) plants in protected areas and their buffer zones, in areas of organic farming, and in areas that are of importance to ecotourism. The law provides a legal tool for excluding most of the country from planting GE plants. Moreover, 14 out of 20 Croatian counties have declared themselves to be GMO free. To date, in Croatia no permits have been granted for the deliberate release of GE plants -- either for field trials or commercial cultivation -- and no food or feed products containing biotechnology have been approved. It is difficult to assess the potential impact on U.S. firms due to these legislative restrictions, but U.S. firms are likely adversely affected.

For more information on the EU-27(28) biotech situation please refer to EU-27 Agricultural Biotech Report.

Section II. Plant and Animal Biotechnology

Chapter 1: Plant Biotechnology

PART A: Trade and Production

a) Product Development: Croatia is not developing any biotech crops.

b) Commercial Production: Croatia does not commercially produce biotech crops or seeds. Croatia's law on Genetically Modified Organisms (GMOs) bans the release of GMOs in protected areas and their buffer zones, in areas of organic farming, and in areas that are of importance to ecotourism. The law provides a legal tool for excluding most of the country from planting GMOs. Moreover, 14 out of 20 Croatian counties have declared themselves to be GMO free. To date, in Croatia no permits have been

granted for the deliberate release of GMOs -- either for field trials or commercial cultivation -- and no food or feed products containing GMOs have been approved. It is difficult to assess the potential impact on U.S. firms due to these legislative restrictions, but U.S. firms are likely adversely affected.

c) Export: Officially Croatia is neither exporting nor importing GE crops/products.

d) Imports: Currently there are no GM labeled products on the Croatian market nor have any GMO foods or feeds been approved for import.

e) Food Aid Recipient Countries: Croatia is not a food aid recipient.

Part B: Policy:

a)Regulatory framework:

The following laws together regulate the importation, transshipment, production, usage, and sale of products of agricultural biotechnology (all food, feed, and seed):

The Law on GMOs (Governmental Gazette 70/2005, 137/2009, 28/2013), the Law on the Application of EU Regulation 1829/2003 on GMO Food and Feed and Regulation 1830/2003 on Traceability and Labeling of Food and Feed Derived from GMOs that Amends EU Directive 2001/18/EC (Governmental Gazette 18/2013), the Law on the Application of EU Regulation 1946/2003 on Trans-boundary Movement of GMOs (Governmental Gazette 81/2013) and the Food Act (Governmental Gazette 81/2013).

The Law on GMOs incorporates the following EU regulations and directives: Directive 2001/18/EC, Directive 2009/41/EC, Regulation 1829/2003, Regulation 641/2004, Regulation 1981/2006, Regulation 1830/2003 and Regulation 65/2004.

The Law on Application of the EU Regulation 1829/2003 on GMO Food and Feed and Regulation 1830/2003 on Traceability and Labeling of Food and Feed Derived from GMOs that Amends EU Directive 2001/18/EC and the Law on Application of the EU Regulation 1946/2003 on Trans-boundary Movement of GMOs came into effect with Croatian EU accession. These two laws establish the responsible bodies and their tasks relating to the handling of biotechnology products as well as the penalties for breaching the provisions of these laws.

The Food Act governs the responsible bodies and their tasks, responsibilities of stakeholders in food and feed handling, official controls and legal measures for the application of the following EU legal documents: Regulation 178/2002, Regulation 1304/2003, Regulation 2230/2004, Regulation 178/2002, Regulation 608/2004, Regulation 115/2010, Regulation 16/2011, Regulation 931/2011, Regulation 178/2002, Regulation 208/2013, Decision 2004/478/EC, Regulation 1760/2000 and all other EU legal acts enacted for application of the before mentioned legislation.

i. Responsible Ministries and Their Roles:

The Ministry of Science (MOS), Education and Sport: According to the Law on GMOs, the MOS is responsible for the limited and contained use of genetically engineered products. If an institute wanted to do research on genetically engineered products, it would have to apply to the MOS.

The Ministry of Health (MOH): According to the Food Act, the MOH is responsible for all issues relating to food, foodstuff, and feed containing biotechnology content and inspections. Additionally, the Law on GMOs proscribes that MOH oversee the usage and inspection of GMO products in cosmetics, pharmaceutical products, and products for human health protection. According to the Law on GMOs, the MOH is the umbrella ministry and coordinating body for all biotechnology issues. Furthermore, the Law on the Application of EU Regulation 1829/2003 on GMO Food and Feed and Regulation 1830/2003 on Traceability and Labeling of Food and Feed Derived from GMOs that Amends EU Directive 2001/18/EC names the Ministry of Health as the lead Ministry for implementation of the mentioned EU Regulations although sometimes the Ministry of Agriculture has to be consulted.

The Service for Biodiversity in the Ministry of Environment Protection and Nature (MEPN): According to the Law on GMOs the Ministry of Culture is responsible for the intentional introduction of GMOs into the environment. In 2012, MEPN replaced the Environment Protection Directorate in the Ministry of Culture (MOC): Furthermore, according to the Law on the Application of EU Regulation 1946/2003 on Trans-boundary Movement of GMOs, this Ministry is responsible implementation of this regulation, MEPN has to coordinate its activities with the Ministry of Health, the Ministry of Agriculture and Croatian Customs.

The Ministry of Agriculture (MOA): According to the Food Act, the Ministry of Agriculture is responsible for coordinating official inspections and is the EU's contact point. According to the Law on GMOs, the MOA has responsibility for inspections of biotech feed; biotech reproduction material in agriculture and veterinary medicine; and drugs in veterinary medicine and pesticides. Furthermore, the MOA is responsible for giving its consent for the intentional release of biotech products into the environment.

The State Inspectorate: According to the Law on GMOs and, the Law on the Application of EU Regulation 1829/2003 on GMO Food and Feed and Regulation 1830/2003 on Traceability and Labeling of Food and Feed Derived from GMOs that Amends EU Directive 2001/18/EC, the State Inspectorate is responsible for inspecting GMO labeling.

ii. Role and Membership of Biosafety Committee (if any):

The Law on GMOs required the establishment of a Council for GMOs with the specific task of assisting governmental bodies to apply the Law. The Council has 17 members appointed by the Government of Croatia based on nominations from the pertinent Ministries. Council membership lasts for four years. The Council's work is independent and public. According to the Law, the Council's tasks include: tracking gene technology development and usage, tracking scientific breakthroughs and giving opinion and incentives for usage of gene technology and GMOs, giving opinions on social, ethical, technical, scientific, and other conditions of GMO use, advising responsible institutions on GMO and gene technology issues, informing the public on GMO and gene technology development, and presenting viewpoints and opinions.

The Law on GMOs also calls for establishing a Board for Limited Usage of GMOs with 11 members composed of scientists from the fields of microbiology, genetics, medicine, biochemistry, molecular biology, pharmacy, biotechnology, agriculture, forestry, veterinary medicine, nature and environmental

protection, and occupational protection. In addition, the Law on GMOs requires the establishment of a board for the introduction of biotech products into the environment that consists of nine scientists from the fields of: genetics, ecology, nature protection, environmental protection, agriculture, forestry, veterinary medicine, biochemistry, molecular biology, microbiology, and medicine. The tasks of these boards include: giving opinions on biotech usage in terms of legal procedures as outlined by the Law on GMOs; giving opinions and proposals for preparing other legislation on GMO usage; and giving opinions and proposals to responsible ministries on biotech usage issues and other expert work as outlined by the GMO Law and related regulations. According to the law, these two boards should report to the GMO Council once a year.

The old and new Food Act/s call for the establishment of a Croatian Food Agency (CFA). The CFA began its work in 2004 and provides scientific and technical support to legislators as well as scientific advice in all areas that directly or indirectly influence food and feed safety. Additionally, the Food Agency provides scientific opinions to the Ministry of Health and the Ministry of Agriculture regarding the placement of GMO food and/or feed on the market.

iii. Assessment of political factors that may influence regulatory decisions related to agricultural biotechnology:

Biotech opponents in Croatia have been emboldened by the perceived success of Austria and Slovenia in standing up to the European Commission on biotech approvals. Thus, complying with EU regulations has little meaning as long as Croatia positions itself within a regional group of “healthy,” GMO-free countries.

Currently, Croatia clearly sees its future as a “niche market for healthy food” (NOTE: In Croatia, the word “healthy” encompasses everything from conventional and organic to non-biotech products). There has been limited demand for biotech seed imports to combat drought, pests, or soil problems. Government officials acknowledge the legal obligation to open their agricultural market to foreign imports, while openly acknowledging they are positioning Croatia as a GMO-free, “healthy” tourist destination. The Croatian public generally is opposed to biotech products.

iv. Distinctions between the regulatory treatment of approval for food, feed, processing, and environmental release are the following:

There are similar long and complicated procedures to approve conventional and biotech food and feed products, but the approval process for environmental release is different. At the end of the regulatory procedure for food and feed, biotech products must gain special permission to market the product. Some agricultural seed varieties (biotech and conventional); however, must first go through a variety registration process. After the Croatian Seed and Seedlings Institute registers the variety, it is placed on the list of seed varieties that can be marketed in Croatia. Biotech seeds, in addition to variety registration, require special permission to be placed on the market, including permission for the intentional environmental release of GMOs.

b) Approvals: Croatia has not approved any biotech crops for food or feed use in Croatia, but there is a 0.9% threshold level for EU approved biotech events in food and feed when labeling is not required. However, if the biotech content is above 0.9%, the product must be labeled. The biotech threshold level

drops to 0.0% for biotech products that are not EU approved. The same applies to feed. Croatia has not approved any biotech seed varieties for planting. In addition, currently there are no seed varieties in the process of being approved. However, Croatia accepts all EU approvals.

c) Field Testing: According to the Law on GMOs and subsequent Regulations, field tests of biotech crops are allowed after all the conditions prescribed by the Law and Regulations are satisfied. However, no such tests are currently being conducted in Croatia.

d) Stacked Event Approvals: Stacked events are treated the same as in the EU. Croatia hasn't issued its own specific guidelines.

e) Additional Requirements: Biotech food and feed products require special permission as GE products to be placed on the market. Additionally, some agricultural seed varieties (regular and biotech) must go through a variety registration process before they are placed on the list of seeds that can be marketed in Croatia. Biotech seeds, in addition to variety registration, require special permission to be placed on the market, including permission for the intentional environmental release of GE plants. However, Croatia accepts all EU approved varieties.

f) Coexistence: The Law on GMOs forbids planting of registered biotech crops in nature-protected areas, ecological areas, areas for organic agricultural production or eco-tourism, protected areas (i.e. as defined as impact zones within previously registered zones), and in areas defined as GMO-free zones by local government. In addition, biotech crop plantings for reproduction are allowed only in the areas that are designated by the Ministry of Agriculture and the Ministry of Environment Protection and Nature and approved by the Croatian Government in a special ordinance.

g) Labeling: According to the Law on the Application of EU Regulation 1829/2003 on GMO Food and Feed and Regulation 1831/2003 on Traceability and Labeling of Food and Feed Derived from GMOs that Amends EU Directive 2001/18/EC, food and feed containing agricultural biotechnology ingredients must have special, additional information on the label that informs consumers of all of its characteristics. A product must be labeled if it contains more than 0.9% of an approved event.

h) Trade Barriers: Beyond current legislation, there is no additional pending, plant-biotechnology legislation with the potential to affect U.S. exports. A potential future exception could be legislation regarding bioengineered animals.

i) Intellectual Property Rights: Biotech crops are not planted commercially in Croatia. Croatia has intellectual property rights legislation in place and is a member of The International Union for the Protection of New Varieties of Plants (UPOV).

j) Cartagena Protocol Ratification: Croatia signed and ratified the Cartagena Biosafety Protocol. Officially, there is no trade in biotech products, especially not in seeds. However, it is currently difficult to tell whether the Biosafety Protocol is being applied and working in practice.

k) International Treaties/Fora: Croatia is a member of the International Plant Protection Convention (IPPC), Codex Alimentarius (Codex), and the World Organization for Animal Health (OIE), but Croatia does not appear to take an active position regarding plant biotechnology in these organizations.

l) Related Issues: Croatia regularly tests products for biotech events at the border and in the market. The testing is performed in accordance with Croatia's annual inspection plans for Sanitary Inspection, which is determined based on available fiscal resources.

m) Low-Level Presence Policy: Croatia follows the EU's technical solution for low-level presence in feed which is that it must be labeled as GE if 0.9% or more of that ingredient has GE content. No technical solution has been adopted for food. If a food ingredient is found to contain more than 0.9% of an approved event it must be labeled. If an unapproved event is detected, it is not permitted to be sold.

Part C: Marketing:

a) Market Acceptance: The average Croatian consumer views food derived from biotech crops negatively. Consequently, many farmers are afraid to grow biotech crops. There is a feeling that biotechnology is something unnatural and food should be natural. These negative opinions are based largely on emotions, not on an informed study of the issue.

b) Public/Private Opinions: The Croatian government is quietly following the EU legislative framework on GE products. However, Croatia has NGOs such as Green Peace and Green Action that are actively campaigning against biotechnology and the Croatian press has generally taken a negative stance on biotech.

c) Marketing Studies: A Croatian market research agency carried out a study in 2009 on "consumer recognition of healthy foods" that among other things researched the opinions and knowledge of Croatian consumers on GMOs. In this study, 51% of respondents said that they would not eat GMO food products under any circumstances and 29% of respondents thought that they did not know enough about GM foodstuffs. The study showed that 90% of respondents thought that GM foodstuffs should be clearly labeled on the store shelves.

The same agency did a study in 2005 and 2008 on public opinion on GMOs. In this study, 67% (2005) and 58% (2008) of respondents said that they would not eat GM food products under any circumstances and only 16% (2005) and 26% (2008) of respondents thought that they didn't know enough about GM foodstuffs.

Part D: Capacity Building and Outreach:

a) Activities: List of the U.S. Government / USDA funded capacity-building / outreach activities that have been carried out in Croatia over the past two years:

2013: Sponsorship of a speaker for a feed conference (KRMIVA): The topic of the conference was Animal Feed. FAS Zagreb provided a speaker on the following topic - "Providing for a safe, sustainable feed and food supply with modern technology and practices in grain and oilseeds production and use".

2012: Sponsorship of two speakers in Sept- Dr. Ralph Scorza, USDA/ARS plant breeding scientist and Victor Felix Nicolescu, member of Romania's National Sanitary, Veterinary and Food Safety Authority. The speakers discussed the US and EU regulatory frameworks and Dr Scorza described his research on a disease resistant GE plum.

2012: Sponsorship of a speaker for a feed conference (KRMIVA): The topic of the conference was Animal Feed and FAS Zagreb provided a speaker on the following topic - "Bt Corn in Italy: a missed opportunity for farmers and feeders".

2011: Sponsorship of a speaker for a feed conference (KRMIVA): The topic of the conference was Animal Feed and FAS Zagreb provided a speaker on the following topic - "Asynchronous Authorization and the Low-level Presence of Unauthorized GMOs and GM-derived Materials in Imports of Feed Commodity Crops from outside the European Union".

b) Strategies and Needs: Further public education campaigns are needed to dispel some of the misinformation circulating on genetically engineered products and to foster a more constructive environment for research and agricultural innovation in this area. More work with the government could also be done to prepare them to participate in international venues like Codex, UPOV, and the OIE.

Chapter 2: Animal Biotechnology:

Part E: Production and Trade

a) Product Development: Genetic engineering and cloning are not practiced in Croatia for the development of agricultural animals.

b) Commercial Production: There are no genetically engineered animals or products derived from the animals intended for or currently in commercial production in Croatia.

c & d) Exports/Imports: Croatia is neither exporting nor importing GE animals, livestock clones, or products from these animals, including genetics (Croatia mainly imports semen, although not knowingly from GE animals or clones). In theory, random testing is conducted, although not specifically for the purpose of identifying whether the animals or animal genetics are GE or cloned.

Part F: Policy

a) Regulation: Beyond EU legislation, Croatia does not have in place any legislation specifically related to the development, commercial use, and/or import of these animals or products.

b) Labeling and Traceability: There are indications that the Croatian Government may consider traceability and mandatory labeling requirements for products derived from GE and cloned animals. The government entities that would likely regulate these technologies for food and environmental safety issues relating to research on or commercial use of these animals include: the Ministry of Agriculture;

the Ministry of Health; the Ministry of Environment Protection and Nature; the Ministry of Science, Education and Sport; the Croatian Food Agency, and the Council for GMOs.

c) Intellectual Property Rights (IPR): Croatia has intellectual property rights legislation in place and is a member of The International Union for the Protection of New Varieties of Plants (UPOV).

d) International Treaties/Fora: Based on consultations, we are unaware of Croatia actively participating in international organization discussions relating to the genetic engineering of agricultural animals.

Part G: Marketing

a) Market Acceptance: The initial reaction to these products is unlikely to be favorable.

b) Public/Private Opinions: There are active organizations that lobby against the genetic engineering or cloning of agricultural animals and Croatia's press historically hasn't been favorable to these types of innovations.

c) Marketing Studies: At this time, there are no known cloning or GE animal production marketing studies.

Part H: Capacity Building and Outreach

a) Activities: Croatia remains opposed to bioengineering in plants and efforts to promote animal biotechnology at this time are unlikely to succeed.

b) Strategies and Needs: Continued work, both with the government and in the arena of public opinion, needs to be done to foster a more favorable environment for technological innovation in the area of food and agricultural production. However, animal welfare issues will continue to play an important role and must be addressed as well.